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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/041,491	03/12/98	SCHWABE	C 07842.047.99

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HM12/0509

EXAMINER

GUPTA, A

ART UNIT

PAPER NUMBER

1653

16

DATE MAILED: 05/09/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/041,491

Applicant(s)

Schwabe et al.

Examiner

Anish Gupta

Group Art Unit
1653



☒ Responsive to communication(s) filed on Apr 13, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 4-6, 11, 12, and 14-20 is/are pending in the application.

Of the above, claim(s) 11 and 12 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 4-6 and 14-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The request filed on 4-13-2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 019/041,491 is acceptable and a CPA has been established. An action on the CPA follows.

2. Applicant's election without traverse of Group I in Paper No. 7 is acknowledged.

Claims 11 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II.

Claim Rejections - 35 USC § 112 *First Paragraph*

3 Claims 4-6 and 14-19 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the previous office action and the reasons set forth below.

Applicants argue that the functional similarities between relaxin like factor and relaxin is a basis of the invention and one of many bases for the treatment of disease with relaxin like factor recited in claims 4-6 and 14-16. Furthermore, the synergistic effects of relaxin like factor on relaxin in vitro and in vivo enables one of ordinary skill in the art to recognize that any conditions susceptible to treatment with relaxin can show a synergistic response to simultaneous treatment. Applicants exemplifying various treatments with relaxin and conclude that due to the functional relationship between relaxin and relaxin like factor, one would expect relaxin like factor to treat such disorders.

Applicants also state that the specification is fully enabled for the full scope of the claims since the claims are drawn to the treatment of a condition susceptible to treatment with relaxin. "[O]ne of ordinary skill in the art could determine conditions susceptible to treatment with relaxin like factor based on those conditions that are susceptible to treatment with relaxin in the course of ordinary experimentation."

Finally, for correlation from in vitro to in vivo efficacy, Applicants make reference to the fact that relaxin like factor binds to the relaxin receptor and therefore the activities cited in the art for relaxin would also correlate to relaxin like factor. Accordingly, the in vivo methods cited for relaxin would correlate to relaxin like factor.

Applicant's arguments filed 4-13-200 have been fully considered but they are not persuasive.

Applicants arguments are based on the fact that since relaxin like factor recognizes the same receptor as relaxin and there are functional similarities in some activities, one of ordinary skill in the art could extrapolate the activities associated with relaxin to relaxin like factor. Although there may be some similarity between activities of relaxin and relaxin like factor, a correlation between all activities attributed with relaxin to relaxin like factor cannot be made without undue experimentation. The art has recognized various drugs that, while in one instance have similar activity, in another instance they completely different activity. For example, Lidocaine and Mexiletine are known to be useful in the treatment of cardiovascular disorders such as arrhythmia. Although Mexiletine is an analog of Lidocaine, both drugs attribute different effects in the treatment of arrhythmias. Lidocaine is effective in treating Ventricular fibrillation, while Mexiletine is not. On the other hand, Mexiletine is effective in treating Ventricular arrhythmias in cardiomyopathy and Ventricular tachycardia while Lidocaine is not. It is known in the art that Lidocaine has substantial first pass hepatic metabolism, while Mexiletine has similar electrophysiologic actions to Lidocaine, but has little or no first pass hepatic metabolism (see page 468 and 474 of the Merck Manual). Another example is the activity of IGF-1 and IGF-2. It is known that although both IGF-1 and IGF-2 recognize the Type I IGF receptor their activity can be quite different. For example, Klempt et al. teach that in a study involving the use of exogenous IGF-1 and IGF2 for the recovery of central nervous tissue after traumatic damage, such as asphyxia, it was found that IGF significantly reduced neural loss, But IGF-2 had no effect (see abstract). Therefore, one of ordinary skill in the art cannot reasonably extrapolate that since two compound exhibit similar activities in certain respects will exhibit similar activities in all respects.

Rejection is maintained.

Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 4-6, 14-15 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

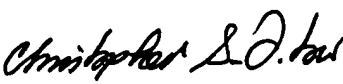
The claims recite a "condition susceptible to treatment with relaxin" and "the condition is ameliorated by softening the pubic ligament or the cervical ligament of the mammal". However, it is unclear what condition is ameliorated since the claims do not recite the condition that is ameliorated by softening the pubic ligament or the cervical ligament.

Accordingly, the claims is indefinite.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta


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